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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,692	09/21/2006	Jun Hirabayashi	20846/0205033-US0	9539
7278	7590	03/01/2010		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER	
			NGUYEN, BAO THUY L.	
			ART UNIT	PAPER NUMBER
			1641	
			MAIL DATE	DELIVERY MODE
			03/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/596,692

Applicant(s)

HIRABAYASHI ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 19-28 and 115 is/are pending in the application.
- 4a) Of the above claim(s) 4-10 and 19-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 11-15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/06)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 10/23/09

DETAILED ACTION

1. The amendment dated 26 October 2009 has been received. Claims 1-15, 17, 19-28 are pending.
2. Claims 4-10 and 19-28 are withdrawn.
3. Claims 1-3, 11-15 and 17 are under consideration.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1—3, 11, 13 and 17 are rejected under 35 U.S.C. 102 (b) as being anticipated by Chan et al (US 2002/0192680) for reasons of records which are reiterated herein below.

Chan discloses a biosensor comprising a substrate having one or more probes which bind to a target molecular coupled to a semiconductor. The probes each include one or more semiconductor-binding groups which enable them to coupled to the semiconductor structure (either directly via a coupling agent), and one or more target binding groups that bind to a target molecule. See paragraph [0040]. If a coupling agent is used, Chan teaches silanes functionalized with an epoxide group, a thiol, or an alkenyl and halide containing compounds. See paragraph [0049]. With respect to silane compounds, Chan teaches 3-glycidoxypopyl trimethoxysilane (GTMS). See paragraph [0050] and [0104]. Chan teaches lectin-glycoprotein, antibody—antigen interaction, etc. see paragraph [0005]. Chan also teaches method for using

the same. See paragraph [0012] and claims 35-38. Chan teaches the use of fluorescence labels. See paragraph [0090].

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chan in view of Mir (US 2004/0248144) for reasons of record which are reiterated herein below.

Chang differs from the instant claim in failing to specifically teach that the excitation light is an evanescent wave.

Mir, however discloses evanescent wave excitation for detecting binding events in biosensors. See paragraphs [0040] and [0203].

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use detect the binding event taught by Chan using evanescent wave excitation because Mir teaches that such technique is conventional and well known in the art.

8. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan in view of Brennan et al (US 2003/0232382).

See the discussion of Chan above. Chan differs from the instant claims in failing to teach the use of rubber to define individual reaction vessels.

Brennan, however, teaches means for separating reactants of one reaction from those of another and to prevent reactants of one reaction from entering another reaction before, during, or after assembly. These methods may include mechanical methods, chemical methods, or combinations thereof. For example, large numbers of reaction wells may be microfabricated on the surface of a solid support with each well providing a reaction site (FIG. 2). In some embodiments, a liquid polymer (such as Self-Seal[®], nail polish, rubber cement, etc.) may be employed as a seal between two arrays or between individual reactions to prevent excess solvent evaporation. Selected areas of a solid support surface may also be chemically or photolytically treated before, during or after assembly to provide separation of reactions. See paragraph [0134].

Even though Brennan does not specifically teach that a rubber having one or more holes is applied onto the glass to define the reaction well, the biosensor of Chan as modified by Brennan results in a device where a layer of rubber material is attached to a glass substrate to define individual reaction wells. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Chan as taught by Brennan because Brennan teaches that it is well known in the art to use materials such as rubber to separate reactants of one reaction area from those of another area. The substrate of claim 14 is obvious over Chan and Brennan because the references teach a product that is the same as, or an obvious variant of, the product set forth in this product-by-process claim although it is produced by a different process.

Response to Arguments

9. Applicant's arguments filed 26 October 2009 have been fully considered but they are not persuasive.

Applicant argues that Chan does not teach measuring the intensity of an excited fluorescence after applying an excitation light *without washing the substrate*.

Chan teaches a method of detecting a target molecule in a sample by exposing the biosensor to the sample under conditions effective to allow binding of a target molecule (i.e. sugar chain or glycoconjugate) with the probes of the sensor. After such exposure, it is determined whether the biological sensor emits a photoluminescent emission pattern which has shifted, indicating the presence of the target molecule in the sample. See paragraph [0062].

Clearly Chan does not teach a *washing step* before a detection step. The recitation cited by Applicant at paragraph [0099] is not persuasive because it is exemplary and does not limit the disclosure.

The argument with respect to claims 2, 3, 11 and 13 are not persuasive because these limitations are all taught by Chan as discussed above.

The argument with respect to the 103 rejection is not persuasive since Chan discloses the invention substantially as claimed except for the use of evanescent wave detection. Mir discloses evanescent wave excitation for detecting binding events in biosensors. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use detect the binding event taught by Chan using evanescent wave excitation because Mir teaches that such technique is conventional and well known in the art.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
February 24, 2010